IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	PATENT
William J. CARROLL et al.	:	GAU: 3762
Serial No.: 10/761,424	:	Confirmation No.: 1421
Filed: January 22, 2004	:	Docket No.: 000309-00053
For: SPINAL CORD STIMULATION WITH INTERFERENTIAL CURRENT	:	Examiner: Joseph A. Stoklosa

DECLARATION OF WILLIAM CARROLL UNDER 37 C.F.R. § 1.132

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22202-3513

Sir:

I, William Carroll, declare as follows:

1. I am the sole inventor of the present application. I am qualified to make this declaration based on my knowledge of the medical device sector, my experience with spinal pain control devices, and my familiarity with prior art devices and the history of spinal cord pain management.

Evidence of Beat Frequency

2. I have reviewed the three references cited by the Examiner in the Office Action dated July 31, 2008. In my view, the references by themselves and in combination do not disclose a beat frequency created by the use of two pairs of electrodes that form an electrical circuit from a signal generator, in which each pair of electrodes carries a sinusoidal signal having a different frequency than the sinusoidal signal of the other pair of electrodes, but when

combined in an additive manner, the two sinusoidal signals create a stronger signal between the two pairs of electrodes.

3. *Carter et al* discloses using a single feed electrode and a return electrode (paragraphs [0013], [0033] and [0051]). In my opinion, *Carter* does not form a beat frequency as a result of interference between a first frequency from a first pair of electrodes and a second frequency from a second pair of electrodes. That is, *Carter* does not teach the interference of a first frequency with that of another frequency to form an additive beat frequency.

Evidence of Long Felt Need

4. The need for an effective electrical stimulation technique for relieving intractable pain has been apparent to those of ordinary skill in the art at least since 1967, when Wall and Street and Shealy et al. developed the theory that electrical stimulation of the dorsal horn of the spinal cord could produce an analgesic effect. However, finding a suitable system that addresses known problems of Spinal Cord Stimulation (SCS) and achieves desired clinical outcomes has proven to be quite allusive.

5. A relatively early report, K. Steglitz in Long-Term Effects of Spinal Cord Stimulation in Chronic Pain Syndromes, Journal of Neurology, 1986, 233: 16-18, summarized that in one study of 50 patients, "only 8 patients had at least some beneficial effect lasting for more than 3 years."

6. In Multifactorial Analysis of Epidural Spinal Cord Stimulation, G. Barolat et al., Stereotact Funct Neurosurg, 1991; 56:77-103, the authors concluded that SCS had, by 1991, been performed for almost two decades, but had not gained uniform approval due to a variety of factors. The authors set out to investigate how to optimize the placement of array/leads and the electrical stimulation parameters for SCS. In their conclusions, Barolat et al. found four keys to optimizing the outcome of SCS: (1) the perception threshold at the impact site should be less

than 3 volts because of battery life considerations; (2) the usage range should be between 0.5-1 volt; (3) stimulation must not activate a strong segmentary band; and (4) the paresthesiae should completely cover the area of the pain. Although they did not consider clinical outcomes in their study, Barolat et al. concluded that successful outcomes would require careful intraoperative array/lead placement and postoperative testing of all the available combinations. Thus, by 1991, certain key electrical and placement factors for SCS had been identified as important. Since Barolat et al.'s study, other study authors and literature reviewers have noted that demonstrated successful outcomes in the area of SCS continue to be lacking, suggesting that practical applications of the key factors had not been developed, and, conversely, would have been desirable to those skilled in the art of SCS.

7. As noted by B. Donner et al., in Long-Term Effects of Nerve Blocks in Chronic Pain, Current Opinion in Anesthesiology, 1998, 11: 523-532, "There is no disease in which different invasive procedures are performed so frequently and so uncritically as in chronic low back pain. Up to now, however, all controlled studies of invasive procedures only demonstrated short-term effects and failed to prove long-term efficacy."

8. By 2002, advances in the technology had still not produced desired outcomes. As noted by R. North in Spinal Cord Stimulation for Chronic Pain of Spinal Origin, Spine, 2002, 27: 2584-2591, by 2002 "the ultimate efficacy of spinal cord stimulation remains to be determined, primarily because of limitations associated with the published literature. However, on the basis of the current evidence, it may represent a valuable treatment option, particularly for patients with chronic pain of predominately neuropathic origin and topographical distribution involving the extremities." North found that the "literature suggests an important role for spinal cord stimulation," also noted that authors concluded that the limitations of the literature must be

acknowledged. North also recognizes that success in pain control techniques had primarily been observed in treating pain in the extremities. His observation is consistent with other references that cite successful outcomes in controlling leg pain, and not, for example, lower back pain.

9. In Spinal Cord Stimulation in Chronic Pain: A Review of Evidence, Anesthesia Intensive Care, 2004, 32: 11-21, published about a month after the present patent application was filed, M.L. Carter noted that by 2004, the efficacy of SCS, at least in connection with treating failed back surgery syndrome, was still inconclusive. Carter concluded that "although 50-60% of patients with failed back surgery syndrome obtain significant pain relief with this technique, the strength of the evidence available is insufficient to clearly advocate its use in all patients with this condition." Carter acknowledged that the lack of high quality evidence concerning the efficacy of SCS had been the result of difficulties in conducting clinical trials: "So far, no study has followed the methodology suggested in the only literature synthesis for studies of spinal cord stimulation in chronic back pain." Indeed, even before the publication of Carter's review and North's assessment two years earlier, it was known by those skilled in the art that stimulation techniques for controlling intractable pain involving the use of electrodes were not generally used by managed care providers because of the lack of demonstrated efficacy.

10. In Spinal Cord Stimulation for Chronic Back and Leg Pain and Failed Back Surgery Syndrome: A Systematic Review and Analysis of Prognostic Factors, Spine, 2004: 30: 152-160, R. Taylor looked at data through 2002 and concluded that "despite an increase in the number of studies over the last 10 years, the level of evidence for the efficacy of spinal cord stimulation in chronic back and leg pain/failed back surgery syndrome remains "moderate." He noted that much of the problem was due to a small amount of controlled evidence, poor quality and reporting of study data, incomplete or inadequate information, and exaggerated reporting.

Taylor reported that since the first report of the electrical stimulation of the spinal cord in 1967, SCS has undergone a variety of technical modifications and advances and has been applied in a variety of pain conditions. Yet, even as late as 2007, an adequately designed SCS system for effective pain relief had not been identified.

11. Indeed, in Spinal Cord Stimulation Versus Conventional Medical Management for Neuropathic Pain: A Multicentre Randomised Controlled Trial in Patients With Failed Back Surgery Syndrome, Pain; 2007: 132:179-88, published three years after Carter's and Taylor's reviews were published, K. Kumar et al. noted that 32% of study patients experienced 40 device-related complications, and that 48% of the SCS group of patients achieve the primary outcome of 50% leg pain relief at both six and twelve months after using implanted stimulators. Although the outcomes were much higher than those for conventional medical management (CMM) techniques, the results are only 50%, which is not compelling evidence of efficacy. Coupled with the relatively high complication rate, those skilled in the art in 2007, and even earlier, would have understood that current implantable electrode stimulation techniques did not satisfy the long-felt need for solving the many problems associated with SCS systems in such a way as to improve clinical outcomes.

12. Thus, it is my view that the need for a properly designed electrode stimulation device has been persistent in the managed care field since 1967. Indeed, there has been a long-felt need in the industry for a design of an SCS system that can minimize complications and effectively provides relief for a variety or neuropathic pain conditions. In particular, as noted in the present patent application, there has been a long-felt need in the industry for a solution to the problems of accommodation or habituation, among other problems, that has been observed in the use of SCS systems. Until those two known problems were addressed by the present invention

and have been adopted by clinicians, it is doubtful that improved outcomes will be observed in any clinical setting.

13. I further declare that all statement made herein of my own knowledge are true and that all statements made herein on information and belief we believed to be true and that all statements are made with the knowledge that willful false statements and the life are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon..

Respectfully submitted,

Date: 11/5/08

William Carroll